## REMARKS

This Amendment responds to the Office Action mailed on December 5, 2005, and the references cited therewith.

No claims have been amended, canceled, or added; as a result, claims 1, 4, 7-22 and 25 are now pending in this application.

*Inherency*

The Examiner has based all of the claim rejections under 35 U.S.C. § 102(b) and 35 U.S.C. § 103(a) on a theory of inherency. The Examiner argues that the claimed method of reducing the number of non-inflammatory lesions of acne is inherent to the method for use of dapsone described in the Osborne '560 and '085 patents. Applicant respectfully submits that the inherency theory fails for both the § 102 and § 103 rejections.

The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993); *In re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' " *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999). Also, "In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." Ex parte Levy, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original). Finally, in the case of chemical compositions, the composition must be considered as a whole that is made up of both its structure and its properties. *In re Papesch*, 315 F.2d 381, 137 USPQ 43 (CCPA 1963).

Applicant will explain why inherency does not exist for each of the bases of rejection in the sections below.

*§102 Rejection of the Claims*

Claims 1, 4, 7, 13, 14, 20, 21 and 25 were rejected under 35 U.S.C. § 102(b) as being anticipated by US 6,060,085 to Osborne or US 5,863,560 to Osborne (as evidenced by Russell, AFP, 2000).

Osborne '085 is a continuation of Osborne '560. In order to simplify the arguments below, Applicant will refer only to Osborne, but the arguments apply to both Osborne '560 and Osborne '085. In addition, the Examiner appears to have mistakenly referred to the '085 patent as the '060 patent (beginning on page 3 of Office Action). Because there is no prior indication of any '060 patent and because the numbers before '085 in Osborne are 060, Applicant assumes that Examiner's '060 is meant to be the '085 Osborne patent.

The Examiner states that while the Osborne patents do not disclose treatment of non-inflammatory acne, nothing in the above references indicate that acne (treated by dapsone of '085 or '560) is not the commonly occurring form (as taught by Russell) and that the acne lesions are only of inflammatory type. Accordingly, the Examiner asserts that both inflammatory and non-inflammatory lesions are inherent to the acne described in '085 and '560 and therefore the claimed method of reducing the number of non-inflammatory lesions is inherent to the teachings of '085 and '560.

To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. The mere fact that a certain thing may result from a given set of circumstances is not sufficient. *In re Robertson, supra.*

Applicant points out that the teaching of Russell, that a mixture of both inflammatory and non-inflammatory acne lesions is the most common situation, does not lead to the conclusion that the method of using dapsone inherently reduces non-inflammatory lesions (in addition to inflammatory lesions). In order to reach the conclusion that Osborne's method inherently results in reduction of both inflammatory and non-inflammatory acne lesions, the Examiner apparently assumes that Russell teaches that a treatment which is successful for reducing one form of acne must necessarily succeed in reducing the other form, simply because both forms of acne are usually present. The Examiner even states (page 5) that "the inherent ability of Dapsone to treat non-inflammatory acne comes from the reference of Russell."

This assumption is incorrect. Russell merely describes the most common situation. Russell does not state, require or infer that a topical antibiotic (such as dapsone) would reduce both inflammatory and non-inflammatory acne.

It was well known in the art at the time of Osborne, and is still common practice today, that topical antibiotics are used to reduce inflammatory acne, not non-inflammatory acne. On page 62 of "Acne: A Review of Optimum Treatment" (Drugs 48(1): 59-70, 1994), Sykes states that "Topical antibiotics are very useful in the treatment of mild to moderate inflammatory acne vulgaris, but probably have no role in treating the comedonal phase of the disease." Russell also shows (Figure 5, Algorithm for the management of acne) that antibiotics are used for treating inflammatory lesions and mixed lesions, but not non-inflammatory comedonal lesions. Finally, Osborne specifically discusses the use of antimicrobials and anti-inflammatory agents (including dapsone, see Column 5), but does not disclose non-inflammatory or comedonal acne (as the Examiner acknowledges). Applicant stresses that antibiotics generally are known ***not*** to treat non-inflammatory comedonal lesions; consequently, a person of ordinary skill in the art would not expect that topical antibiotic dapsone would necessarily reduce non-inflammatory acne lesions. Thus, inherency has not been established.

Additionally, the Examiner has failed to show a basis in fact and/or technical reasoning to reasonably support the determination that dapsone necessarily reduces non-inflammatory acne, based on the teachings of the applied prior art. To conclude that dapsone necessarily reduces non-inflammatory acne, the Examiner apparently assumes that topical dapsone has actually been *used* in practice to treat acne, and that each and every time topical dapsone has been used, non-inflammatory lesions have been reduced because of its inherent abilities.

This assumption is incorrect. Although Osborne discloses use of topical dapsone for the treatment of acne, this process was not actually performed at the time Osborne filed the '085 patent. Thus, examples 9, 10, and 11 (columns 12-14) in Osborne are the only instances in which dapsone was applied to human skin, and that skin was removed from cadavers. The dapsone was applied to the cadaver skin to determine permeation into the skin and retention on the skin's surface, not to assess reduction of acne lesions. Thus, because he has no actual working examples of treatment of living skin having acne, Osborne does not demonstrate *actual use* of topical dapsone in treating acne for a living person.

Indeed, the first actual use of topical dapsone in treating any type of acne was in the clinical studies described in the current invention. This use was attendant to the approval of dapsone for inflammatory acne treatment by the Food and Drug Administration (approved July 7, 2005). The first use of topical dapsone to treat non-inflammatory acne is the very genesis of the current invention. The absence of prior actual use of topical dapsone in *any* type of acne treatment before the current invention shows that inherency cannot attach. The Examiner's theory that the actual use of dapsone to treat acne inherently treated non-inflammatory acne fails because there was no such prior use! Moreover, Applicant points out that the teachings in the prior art that dapsone, an antibiotic, would only be expected to reduce inflammatory lesions, and would not lead a person of ordinary skill in the art to recognize that topical dapsone could reduce non-inflammatory acne. That recognition, either by actual use or by realization, is the cornerstone of inherency. Neither is present for the current situation. Thus, the method of treating and reducing the number of non-inflammatory acne lesions is not inherent to the teachings of '560 and '085.

Furthermore, in the case of chemical compositions, the composition must be considered as a whole that is made up of both its structure and its properties. *In re Papesch*, 315 F.2d 381, 137 USPQ 43 (CCPA 1963). Because of dapsone's anti-microbial properties, one of ordinary skill in the art would have expected topical dapsone to reduce inflammatory acne, but would not have been able to predict a non-inflammatory property. In the detailed description section of the current application (page 4), Applicant explains that because the *P. acnes* bacterium is not considered a primary factor in the development of non-inflammatory lesions, it would be unexpected that topical dapsone would significantly reduce the number of non-inflammatory lesions. However, the data show that non-inflammatory lesions were indeed reduced. This unanticipated, surprising property of dapsone is the essence of the present invention and is separate from its anti-microbial property. The process of using topical dapsone surprisingly achieved the result of reducing non-inflammatory acne lesions. Thus, there is no inherent ability of the composition of dapsone of Osborne to reduce non-inflammatory acne.

Finally, in her argument that topical dapsone inherently reduces non-inflammatory acne, the Examiner asserts (page 5 of Office Action) that because Osborne teaches that the antimicrobial and anti-inflammatory actions of dapsone need not necessarily be related to each

other, the anti-microbial action of dapsone need not necessarily be related to anti-inflammatory activity and hence can be considered as non-inflammatory.

This assertion is also incorrect. The Examiner has apparently disregarded the fact that microbial activity is a direct cause of inflammation in acne, and that anti-microbials reduce inflammatory acne by reducing microbial activity. Not all inflammation is caused by the presence of microbes; however, if microbes are present, inflammation is necessarily triggered. It is well known that the presence and proliferation of *P. acnes* bacteria leads to the development of inflammatory acne lesions (Russell, page 2) and that topical antibiotics reduce acne directly by killing *P. acnes* (Sykes, page 62; Russell, page 8). One of ordinary skill in the art would recognize that the direct anti-microbial activity of dapsone necessarily reduces inflammation by virtue of killing *P. acnes*. Additionally, Osborne does not include any other, additional action of dapsone's anti-microbial property besides its anti-inflammatory action. Therefore, the Examiner has no basis for concluding that dapsone's anti-microbial action can be considered non-inflammatory. The anti-microbial action of dapsone is necessarily related to its anti-inflammatory activity.

Withdrawal of this rejection is respectfully requested.

*§103 Rejection of the Claims*

Claims 8-12, 15-19 and 22 were rejected under 35 U.S.C. § 103(a) as being unpatentable over US 6,060,085 in view of Russell and US 6,200,964 to Singleton et al. OR over US 5,863,560 ('560) in view of Russell and US6,200,964 to Singleton et al.

The Examiner recognizes that Osborne does not disclose cream, lotion, spray, suspension, or ointment formulations. In order to overcome this deficiency, she has cited Russell and Singleton et al., and has explicitly carried over her inherency argument from the § 102(b) rejection above, that the ability to treat non-inflammatory acne is inherent to the composition of dapsone of Osborne. The Examiner asserts that it would have been obvious to one of an ordinary skill in the art at the time of the instant invention to optimize the amount of dapsone and choose the type of the formulation, depending on the type of skin and also depending on the solubility of the compound, with an expectation to achieve the desired effect (treatment of acne lesions – both types).

Applicant reiterates that there is no inherent ability of the composition of dapsone of Osborne to reduce non-inflammatory acne. Applicant refers to the foregoing discussion as the basis for this response. Applicant therefore respectfully requests withdrawal of this rejection.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation either in the cited references themselves or in the knowledge generally available to an art worker, to modify the reference or to combine reference teachings so as to arrive at the claimed method. Second, the art must provide a reasonable expectation of success. Finally, the prior art reference must teach or suggest all the claim limitations (M.P.E.P. § 2143). The teaching or suggestion to arrive at the claimed method and the reasonable expectation of success must both be found in the prior art, not in Applicant's disclosure (M.P.E.P. § 2143 citing with favor, *In re Vaeck*, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991)).

Applicant explains that the absence of inherency of the dapsone of Osborne to reduce non-inflammatory acne precludes a finding of obviousness under § 103. Russell and Singleton do not disclose dapsone, and nothing in Osborne or the knowledge generally available to an art worker would lead one to treat non-inflammatory acne with dapsone. As discussed above, antibiotics historically were, and currently are, used to treat inflammatory acne, not non-inflammatory acne. In addition, there was no actual use of topical dapsone in treatment of acne (of any type) before the clinical studies that were the genesis of the current invention. Furthermore, the discovery of the ability of topical dapsone to reduce non-inflammatory acne lesions was unanticipated and surprising, which can rebut a *prima facie* case of obviousness. *In re Papesch, supra.* Therefore, there is no suggestion or motivation either in the cited references themselves or in the knowledge generally available to an art worker to modify or combine the reference teachings to use dapsone for non-inflammatory acne, and there would be no reasonable expectation of dapsone's success in reducing non-inflammatory lesions. Thus, the Examiner has not established a *prima facie* case of obviousness. Withdrawal of this rejection is respectfully requested.

## CONCLUSION

Applicant respectfully submits that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney at (612) 373-6939 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

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Date March 15, 2006

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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Mail Stop Amendment, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 15th day of March, 2006.

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